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09/598,604	06/21/2000	Barbara B. Lamb	50172/002001	7546

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/29/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/598,604

Applicant(s)

LAMBI, BARBARA B.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,5-7,9,10,12,14-17,19-21 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 35 is/are allowed.
- 6) ☐ Claim(s) 1,5-7,9,10,12,14-17,19-21,36 and 37 is/are rejected.
- 7) ☐ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

New claims 35-37 have been added.

Claims 2,8,11,13,18,22-34 have been canceled.

Claims 1, 5-7,9-10,12, 14-17 have been amended.

Claims 1, 5-7,9-10,12, 14-17, 19-21, and 35-37 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Request for Continued Examination

1. The request filed on April 4, 2003 for a Request for continued Examination under 37 CFR 1.114 based on parent Application No. 09/598, 604 is acceptable and a RCE has been established. An action follows.

Allowable Subject Matter

2. Claim 35 defines over the prior art of record and is therefore allowed.
3. Claim 16 would be allowable if rewritten to only depend from claim 14.

Objections/Rejections Withdrawn

4. The disclosure objected to because of the following informalities: at page 13, line 6 the phrase "(Rule 28(4)EPC)", in light of the amendment of the specification to provide a clarifying explanation of this phrase.
5. Claims 6,10, 12 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from preceding claims in the alternative; claims 6, 10 and 12 depend from claims 22-24 which are not preceding claims, in light of the amendment of the claims to no longer be multiple dependent claims.
6. Claims 6-9, 10-11, 12-13 objected to as being dependent upon withdrawn claims 22-24, in light of the amendment of the claims to no longer be multiple dependent claims.
7. Claims 1-21, 32-34 are rejected under 35 U.S.C. 112, first paragraph (paper number 8, paragraph 74), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

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the application was filed, had possession of the claimed invention. All of the claims recite the claim limitation "forming periodic colonies of 2 to 10,000 cells" or in the case of claim 18 "colonies are 2 to 1000 cells". No original descriptive support for these limitations could be found has been herein withdrawn, in light of the cancellation of claims and amendment of others to no longer recite the combination of claim limitations not evidencing original descriptive support in the instant specification.

8. Claims 5-13 rejected under 35 U.S.C. 112, second paragraph, for not distinctly claiming what is detected, in light of the amendment of the claims to recite detection of an organism with a plurality of characteristics.

9. Claims 5-8, 10-13 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, in light of the amendment of the claims to recite an organism with a plurality of characteristics.

10. Claim 17 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of claim 17 to be an independent claim, which recites a plurality of characteristics of the organism to be treated.

11. Claims 1-2, 5, 7, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in paper number 8, paragraph 75, in light of the cancellation and amendment of the claims to clarify the claimed invention.

12. Claims 5, 10 rejected under 35 U.S.C. 102(b) as being anticipated by Caillouette et al (US Pat 5,827,200), in light of the amendment of the claims to recite protozoa, rather than SPR that could be either a bacteria or protozoa and Caillouette et al disclose bacteria.

13. Claims 5, 10 rejected under 35 U.S.C. 102(e) as being anticipated by Caillouette et al (US Pat. 5,928,165), in light of the amendment of the claims to recite protozoa, rather than SPR that could be either a bacteria or protozoa and Caillouette et al disclose bacteria.

14. Claims 14-15, and 16 rejected under 35 U.S.C. 102(e) as being anticipated by Caillouette et al (US Pat. 5,928,165), in light of the amendment of the claims to recite "hollow loop".

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15. Claim 15, as previously applied to claim 16 rejected under 35 U.S.C. 102(b) as being anticipated by Caillouette et al (US Pat. 5,577,512; or 5,425,377), in light of the amendment of the claims to recite "hollow loop".

16. Claims 5-8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US Pat. 5,928,165) in view of Kalb et al (US Pat. 5,704,353) in light of the amendment of the claims to recite protozoa rather than SPR.

17. Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US Pat. 5,928,165) in view of Kalb et al (US Pat. 5,704,353) as applied to claims 5-8, 10-11, further in view of Sheiness et al (US Pat. 5,776,694, in light of the amendment of the claims to recite protozoa rather than SPR.

18. Claims 5-7 rejected under 35 U.S.C. 102(b) as being anticipated by Mennen (US Pat. 4,108,729), in light of the amendment of the claims to recite protozoa rather than SPR.

19. Claims 5, 12 rejected under 35 U.S.C. 102(b) as being anticipated by Yeh (US Pat. 5,725,373), in light of the amendment of the claims to recite protozoa rather than SPR.

20. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Gray (US Pat. 5,474,997), in light of the amendment of the claim to no longer include treatment of SPR bacterial infection.

Objections/Rejections Maintained

21. Claims 1, 19-21 (cell claims); 5, 7, 10, 12 (method claims) rejected under 35 U.S.C. 102(b) as being anticipated by Abou El Seoud (April 1998) for reasons of record in paper number 4, paragraph 14 . and for reasons of record in paper number 4, paragraph 17.

22. Claims 1, 19-21 rejected under 35 U.S.C. 102(b) as being anticipated by Monteiro-Leal et al (1996), for reasons of record in paper number 4, paragraph 15 as applied to claims 1-4.

23. Claim 5, 10 rejected under 35 U.S.C. 102(b) as being anticipated by Andrews et al (US Pat. 5,300,491), for reasons of record in paper number 4, paragraph 18.

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24. Claim 17 rejected under 35 U.S.C. 102(b) as being anticipated by Birthistle et al (1996), for reasons of record in paper number 4, paragraph 26.

25. Claim 17 rejected under 35 U.S.C. 102(b) as being anticipated by Larson(US Pat. 6,180,136), for reasons of record in paper number 4, paragraph 27.

Response to Arguments

26. Applicant's arguments filed April 9, 2003 have been fully considered but they are not persuasive.

27. The rejection of claims 1, 19-21 (cell claims); 5, 7, 10, 12 (method claims) rejected under 35 U.S.C. 102(b) as being anticipated by Abou El Seoud (April 1998) is traversed on the grounds that: El Seoud does not use Diamond medium for growth/isolation of *Trichomonas vaginalis*; nor does the reference describe any organism that exhibits periodic colonial clustering.

28. It is the position of the examiner that at page 264, paragraph 3, two different growth media were inoculated for growth and isolation of *Trichomonas vaginalis*, wherein one of the media was Diamond's medium (see page 265, paragraph 1, middle of paragraph).

With respect to arguments directed to the phrase "periodic colonial clustering" which has been asserted to define a functional characteristic and patentable novelty of the claimed compositions, it is the position of the examiner that this phrase is not an art recognized phrase to describe bacterial or protozoan growth. When a biological sample is streaked out on a selective growth medium containing petri dish, the goal is to obtain isolated colonies of a pure culture of a microorganism. The isolated colonies are clusters of cells, but the location of the clusters is random based upon where the application tool distributes the sample. How a regular, periodic growth pattern that results in a standardized periodic colonial cluster of cells which produces a pattern of growth and distinguishes one protozoan from all others has not been clearly defined in the instant specification, nor exists as a diagnostic standard in the art of parasitology. Isolates of the protozoan of El Seoud would periodically produce colonies, which would result in clusters of cells based upon the isolation technique used for isolation of the protozoan on Diamond medium. A single cluster of cells would originate from a single cell that replicates into colony containing many cells. Applicant's arguments have not distinguished the claimed invention from the applied prior art. The rejection is maintained from reasons of record.

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29. The rejection of claims 1, 19-21 under 35 U.S.C. 102(b) as being anticipated by Monteiro-Leal et al (1996), is traversed on the grounds that:

Monteiro-Leal et al does not describe an organism that exhibits periodic colonial clustering, can live as both a single solitary organism and an organism in a clustering colony.

30. It is the position of the examiner that Monteiro-Leal et al disclose a biologically pure culture of a single celled organism (see Figure 1, page 207), that was cultured to produce a large colony of the protozoan (see page 207, col. 1, Cells, "cultured in TYM medium [Diamond, 1957] medium. Figure 1 shows a single cell and the culture contained a large colony of cells.

Applicant arguments have not distinguished the claimed invention over the applied prior art. Protozoa prior to infection of a new host exist as single cells, which replicate and produce a colony cluster of new cells. Monteiro-Leal et al anticipate the claimed invention.

31. The rejection of claim 5, 10 under 35 U.S.C. 102(b) as being anticipated by Andrews et al (US Pat. 5,300,491), is traversed on the grounds that Andrews et al does not describe an organism that exhibits periodic colonial clustering.

32. It is the position of the examiner that Andrews et al does obtain a sample for a patient and tests the sample for the presence of an organism that has the recited characteristics. The test method is not limited to any specific series of methods steps for identification of the organism, but the organism must evidence the recited characteristics. The tests are not limited to culturing and morphological identification of the organism; PCR identification could be used, but the resulting organism identified by the testing must have the recited characteristics.

Andrews does carry out the method steps of **obtaining** a sample from a patient, wherein the sample (col. 8, line 67; col. 13, lines 53; col. 18, lines 27-29) is a human sample (T. vaginalis , see col. 13, lines 52-54);

testing for the presence of a single celled organism that is spiky and rotating (motile protozoan) (samples were cultured, a type of testing: col. 8, line 68 and col. 9, line 33; col. 13, lines 53-55 (antibiotic sensitivity characterization); col. 18, lines 27-29). The SPR infection causing pathogen diagnosed by Andrews et al, is a protozoan , the protozoan evidencing the recited characteristics. Andrews et al anticipates the now claimed method of diagnosing infection in a human patient that has "SPR".

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33. The rejections of claim 17 under 35 U.S.C. 102(b) as being anticipated by Birthistle et al (1996); and claim 17 rejected under 35 U.S.C. 102(b) as being anticipated by Larson(US Pat. 6,180,136) are traversed on the grounds that : “[T]he method of present claim 17 first requires diagnosing the presence of an SPR infection organism which causes a disease in humans.

34. It is the position of the examiner that Bristhistle and Larson both diagnose a disease in a patient that are caused by a SPR (Monteiro-Leal et al and El-Seoud provide evidence of protozoan species that meet the functional limitations recited in the claims, and the organisms treated by Bristhistle and Larson are protozoan organisms), wherein the patient may be a mammal, specifically a human. Claim 17 does not recite the term “human” as argued by Applicant, but recites the term “patient”. Never-the-less the examiner will point out that

- a. Birthistle (AIDS, is a human disease, see page 445, col. 1, paragraph 1) teaches the treatment of human patients; and Larson (see col. 6, lines 32-37) teaches the treatment of any mammal; humans are mammals. The references inherently anticipate the claimed invention.

New Claims and Claim Limitations/New Grounds of Rejection

Claim Objections

35. Claim 16 is objected to because of the following informalities: Claim 16 depends from itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

36. Claim 1, 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to a genus of single-cell organisms spiky rotating cells that have seven recited biological characteristics, but only a single species of SPR cell has been described. A single species does not describe the claimed highly variable genus of cells that may have any number or type of spiky membrane projections, and is a provisional protozoan. How additional species of the claimed genus would be similar or different from the single

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disclosed species of SPR has not been described. What has not been described, has not been enabled. The full scope of claim 35 has been enabled, but not the full scope of claims 1, 19-21, which has only been enabled by the single species of invention disclosed.

37. Claims 1, 5-7, 9-10, 12, 16, 17, 19-21 and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 depends from itself and therefore is unclear.

Claims 1, 5-7, 9-10 and 12, 17, 19-21 and 36-37 recite the phrase "periodic colonial clustering". This phrase is not an art recognized phrase to describe a specific phenotypic or genotypic biological or chemical characteristic of bacterial or protozoan growth. When a biological sample is streaked out on a selective growth medium containing petri dish, the goal is to obtain isolated colonies that start from a single cell, to produce (grow out) a pure culture of a microorganism, a cluster of cells. The location of the clusters is random based upon where the application tool distributes the sample. How a regular periodic growth pattern that results in a standardized periodic colonial cluster of cells which produces a pattern of growth distinguishes one protozoan from all others has not been clearly defined in the instant specification, nor exists as a diagnostic standard in the art of parasitology. The phrase "periodic colonial clustering" does not distinctly claim Applicant's invention.

Claim Rejections - 35 USC § 102

38. Claims 5, 7, 9, 10, 19, 20-21, 36-37 are rejected under 35 U.S.C. 102(a) as being anticipated by van der Schee et al (Dec. 1999).

Van der Schee et al disclose a method of diagnosing an SPR infection, a type of protozoan infection, the method comprising the steps of:

(instant claim 5) Obtaining a sample from a human patient (see title, abstract);

Testing the sample for the presence of an organism that causes disease in humans (see abstract);

(Instant claim 7) male urethra sample of urine (see abstract, 5 lines from bottom)

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(Instant claim 9) The testing comprising the step of admixing the sample with saline and examining the sample by microscopy (see page 4127, abstract, “placed in phosphate buffered saline” and used for “microscopy”);

(Instant claim 10) female vaginal sample (vaginal epithelium, see page 4129, col. 2, paragraph 1, four lines from bottom; cervical cancer association, see page 4127, col. 1, paragraph 1, last three lines)

(Instant claim 21, 36) fluid of the genital tract (see title, vaginal swabs and urine (see title);

(Instant claim 20) the disease is non-gonococcal urethritis (see page 4127, col. 1, line 4);

(instant claim 21, 37) wherein the organism proliferates in Diamond Media (see page 4127, abstract and page 4128, col. 1, paragraph 2, bottom half of paragraph). The reference anticipates the instantly claimed invention.

39. Claims 5-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Kritzman et al (US Pat. 5,660,790).

Kritzman et al disclose the instantly claimed invention directed to a method of diagnosing an SPR infection, specifically a protozoan infection, the method comprising the steps of:

Obtaining a sample from a patient (vaginal discharge, see col. 7, line 58);

Testing the pH of the sample (a pH greater than 5.0 indicates the possibility of the presence of *Trichomonas vaginalis* (see col. 7, lines 58-63);

Testing the sample for the presence of an organism (carrying out an immunoassay for the presence of an organism (see col. 10, line 29; col. 9, lines 62-67 and col. 10, lines 1-34). The reference anticipates the instantly claimed invention .

40. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Bush et al (1985).

Bush et al disclose the instantly claimed invention directed to an instrument that comprises: a handle (a portion that is steerable and “maneuverable”, see page 797, col. 1), and a means that comprises a loop region (see Figure 3, Frame B, which shows a loop). (see page 797, col. 1, “Steerable loop-snare). The reference anticipates the instantly claimed invention.

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41. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Nucci (US Pat. 5,063,930).

Nucci disclose the instantly claimed invention directed to an instrument for collecting a sample of a female patient, wherein the sample comprises a cervical vaginal secretion, the instrument comprising:

A handle portion (see Figure 1, #1);

A means for the collecting the secretion, comprising a loop region with an opening (see Figure 2, #2). The loop region is a hole of 8-12 mm in diameter, which opens into a pipe, the wall of which has one or more indicators for pH determination (see col. 2, lines 9-22). The reference anticipates the instantly claimed invention.

42. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Hardy (US Pat. 2,644,879).

Hardy disclose the instantly claimed invention directed to an instrument for collecting a sample of a female patient (females have vaginas and males do not), wherein the sample comprises a cervical vaginal secretion (see col. 1, line 9), the instrument comprising:

A handle portion (see Figure 1, #11, shank);

A means for the collecting the secretion(see Figure 1, #20), comprising a loop region with an opening (see Figure 1, #16). The instrument comprising one or more indicators for pH determination (see Figures 3 and 4). The reference anticipates the instantly claimed invention.

Conclusion

43. This is a non-final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 872-9306.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

October 15, 2003


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